UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,325	05/04/2007	Daniel Thommen	07-2352	5751
20306 7590 09/28/2009 MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606		EXAMINER		
		TEMPLETON, CHRISTOPHER L		
			ART UNIT	PAPER NUMBER
			3773	
			MAIL DATE	DELIVERY MODE
			09/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary  The MAILING DATE of this communication appeared for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING I	Application No.  10/588,325  Examiner  CHRISTOPHER L. TEMPLETON  opears on the cover sheet with the cover sheet wi	Applicant(s) THOMMEN ET AL.  Art Unit 3773
The MAILING DATE of this communication appeared for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING I	Examiner CHRISTOPHER L. TEMPLETON	Art Unit
The MAILING DATE of this communication appeared for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING I	CHRISTOPHER L. TEMPLETON	
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING I		3773
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING I	pears on the cover sheet with the c	3113
A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING I	<b>,</b>	orrespondence address
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If NO period for reply is specified above, the maximum statutory perior</li> <li>Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the mailie earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>	DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin I will apply and will expire SIX (6) MONTHS from te, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).
Status		
Responsive to communication(s) filed on <u>03</u> .  2a)  This action is <b>FINAL</b> . 2b)  The 3) Since this application is in condition for allowed closed in accordance with the practice under	is action is non-final. ance except for formal matters, pro	
Disposition of Claims		
4)  Claim(s) 1-14 is/are pending in the applicatio 4a) Of the above claim(s) 14 is/are withdrawn 5)  Claim(s) is/are allowed. 6)  Claim(s) 1,2 and 9-13 is/are rejected. 7)  Claim(s) 3-8 is/are objected to. 8)  Claim(s) are subject to restriction and/	from consideration.	
9) The specification is objected to by the Examir 10) The drawing(s) filed on <u>03 August 2006</u> is/are Applicant may not request that any objection to the Replacement drawing sheet(s) including the corre 11) The oath or declaration is objected to by the E	: a)⊠ accepted or b)☐ objected to e drawing(s) be held in abeyance. See ction is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Burest*  * See the attached detailed Office action for a list.	nts have been received.  Its have been received in Applicationity documents have been received in Application (PCT Rule 17.2(a)).	on No ed in this National Stage
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 8/3/06.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate

Art Unit: 3773

### **DETAILED ACTION**

#### Election/Restrictions

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species A: Figures 1-6

Species B: Figure 7

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-13 read on species A and claim 14 reads on species B.

The following claim is generic: Claim 1.

- 3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons.
- 4. The special technical feature of species II, a compressible body, is not shared in group I. Therefore, the respective groups lack the same or corresponding special technical features and do not relate to a single general inventive concept, a posteriori, since the implant for occluding a passage in a circulatory system is not a technical feature that defines a contribution over the prior art. Freudenthal et al (WO 01/49185) discloses claim 1.

Art Unit: 3773

Lack of unity of invention may be directly evident "a priori," that is, before considering the claims in relation to any prior art, or may only become apparent "a posteriori," that is, after taking the prior art into consideration. For example, independent claims to A+X, A+Y, X+Y can be said to lack unity a priori as there is no subject matter common to all claims. In the case of independent claims to A+X and A+Y, unity of invention is present a priori as A is common to both claims. However, if it can be established that A is known, there is lack of unity a posteriori, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.

- 5. During a telephone conversation with Steve Courtright on 21 September 2009 a provisional election was made without traverse to prosecute the invention of species A, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claim 14 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

# Claim Objections

- 7. Claim 1 is objected to because of the following informalities: It appears that "reducible" is misspelled "reduceable" in claim 1.
- 8. Claim 7 is objected to because of the following informalities: The word "positions" in line three of the claim should be replaced with "portions".

  Appropriate correction is required.

Claim Rejections - 35 USC § 112

Art Unit: 3773

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 10. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by "the implant forming in a first state an elongated article extending along a longitudinal axis" in line 9 of the claim. For examination purposes, it was read as meaning the implant forms an elongated article (or an elongated structure), which extends along a longitudinal axis.
- 11. Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the occluding bodies having a compressed form in the first state within claim 10. The occluding bodies having an extended or a compressed form is not disclosed.

# Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 13. Claims 1, 2, 9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Freudenthal et al (WO 01/49785).
- 14. As to claim 1, Freudenthal discloses an implant for occluding a passage in a circulatory system, the implant comprising a plurality of thin elongate members 2 each

Application/Control Number: 10/588,325

Art Unit: 3773

Page 5

having a first end and a second end; a first holder 1 to which the first ends of the elongate members are attached; a second holder 12 (Figure 7) to which the second ends of the elongate members are attached, the elongate members being attached to the first and second holders; a first occluding body 8 (Figure 7) being attached to the elongate members. The implant forms in a first state (Figure 1) an elongated structure extending along a longitudinal axis (Figure 1), the implant being adapted in the first state for insertion into to the circulatory system and the implant being adapted to be brought into a second state in the circulatory system, wherein the distance between the holders being reducible in a manner to cause the elongate members to execute a twisting motion relative to the axis to yield a plurality of generally radially extending loops forming at least one fixation structure (Figure 7), thereby increasing a crosssection of the occluding body and the at least one fixation structure being fixable in the second state (Figure 7), and wherein the implant comprises at least one second occluding body 8 (page 14, lines 33-37) (Freudenthal discloses the occluding body 8 as being positioned on different sides of the implant) being attached to the elongate members at a distance to the first occluding body (page 14, lines 33-37) and wherein the distance between the first and the second occluding body is reducible by reducing the distance between the two holders 1, 12 (Figure 7), wherein a fixation structure (Figure 7) is formed between the first occluding body 8 and the first holder 1.

15. As to claim 2, Freudenthal discloses the first and second fixation structures as being formed in the second state (Figure 7).

Art Unit: 3773

16. As to claim 9, Freudenthal discloses the implant in the second state wherein the first 8 and the second occluding body 8 have a cross-section having the same size (Figure 7 and page 14, lines 33-37) (Freudenthal discloses the occluding body 8 as being positioned on different sides of the implant). Implicitly, they would be the same size since both 6 and 7 are the same size (Figure 7).

17. As to claim 13, Freudenthal discloses the elongate members having the same length (Figures 8-9c show it the best).

# Claim Rejections - 35 USC § 103

- 18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 19. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freudenthal et al (WO 01/49785) in view of Solymar (U.S. Patent No. 6,488,706). Freudenthal discloses the claimed invention except for the elongate members extending through the holes of the occluding body. Solymar teaches elongate members extending through the holes of the occluding body Figures 11-13). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the implant of Freudenthal to include the elongate members extending through the occluding body for the purpose better securing the occluding member to the elongate members.

## Allowable Subject Matter

Art Unit: 3773

20. Claims 3-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

21. The following is a statement of reasons for the indication of allowable subject matter: The prior art failed to disclose an occluder with two occluding bodies wherein the elongate members have a first portion arranged between the first holder and the first occluding body and a second portion arranged between the second holder and a second occluding body and a third portion arranged between the first and second occluding bodies.

#### Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Neuss et al (U.S. Patent No. 6,355,052) discloses an occluder with a plurality of elongate members and an occluding body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER L. TEMPLETON whose telephone number is (571) 270-1477. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie T. Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. L. T./ Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/ Supervisory Patent Examiner, Art Unit 3773